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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,252	06/27/2001	Peter Styczynski	00216-552001 / H-245	1872
26161	7590	10/19/2005	(KAY)	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/893,252

**Applicant(s)**

STYCZYNSKI ET AL.

**Examiner**

Gina C. Yu

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 and 52-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 16, 2005 has been entered. Claims 1-48 and 52-55 are pending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 55 recites "a dermatologically acceptable non-depilatory composition". The specification does not define what the metes and bounds of the scope of this limitation are. The claim is deemed vague and indefinite.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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**Claims 1-48 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over West et al. (US 6368789 B1) and Black (WO99/19466) in view of applicants' own admission and Styczynski et al. (US6,020,006).**

West et al. teach a method for treatment of a condition associated with an elevated level of telomerase activity within a cell, which involves administering to that cell a therapeutically effective amount of an inhibitor of telomerase activity. See col. 10, lines 43 – 47. Telomerase inhibitors AZT, d4T (3'-deoxy-2:3'didehydrothymidine), (TTAGGG)<sub>3</sub>, and ddl (dideoxyinosine), among others, are taught. See col. 49, line 40 – col. 54, line 48. The reference teaches that activators of telomerase forestalls and reverses cellular senescence, including hair follicle cells which causes hair loss. See col. 10, lines 9-24. Since the reference teaches that the activation of telomerase can delay and reverse the aging of hair follicle cells, a skilled artisan would have obviously envisioned that the inhibitors of telomerase would reduce hair growth.

Black teaches thymidine kinase mutants and fusion proteins having thymidine kinase and guanylate kinase activity. See page 32 for a teaching of nucleoside analogues, such as AZT, as depilatory reagent that destroy hair follicles. The reference specifically states that within other embodiments of the invention, methods are provided for inhibiting the growth of or destroying cells, which are not traditionally associated with a disease . . .to destroy hair follicles (as a depilatory reagent).

Applicants admit in specification p. 3-4 that the recited telomerase inhibitors are known in publications. Since the telomerase inhibitors taught in

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West et al. and Black are known to reduce hair growth, it would have been obvious to a skilled artisan that other telomerase inhibitors would also induce the same effects. See instant claims 2-6, 8, 9, and 13-32.

The combined references fail to teach the specific mode of topically applying the telomerase inhibitor.

Styczynski et al. teach the reduction of hair growth, see title. Specifically taught is a method of reducing mammalian hair growth which comprises selecting an area of skin from which reduced hair growth is desired, and applying to said area of skin a dermatologically acceptable composition comprising an inhibitor of alkaline phosphatase in an amount effective to reduce hair growth, see Col. 6, lines 12-19 of the reference. For the inhibitor comprising 0.1-30% of the composition, see Col. 6, lines 31-32 of the reference. For a reduction of hair growth of at least 30% and 50% when tested in the Golden Syrian hamster assay, see Col. 6, claims 9-10 of the reference. For the inhibitor applied to the skin in an amount of from 10-3000 micrograms per square centimeter of skin, See Col. 6, claim 11 of the reference. For application to a human, to the face, to the leg, to the arm, to the armpit, to the area of skin in conjunction with shaving and to the torso, see Col. 6, claims 13-18 of the reference. For a woman suffering from hirsutism and androgen stimulated hair growth, see Col. 6, claims 19-20. For application once or twice a hair for 2 days (i.e., 48 hours), see Col. 3, line 66-Col. 4, line 12.

Given the suggestion and teaching of West et al. and Black that inhibitors of telomerase reduce hair growth or depilate the hair follicle cells, one of ordinary

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skill in the art at the time the invention was made would have been motivated to look to the prior art such as Styczynski for a specific mode of topical administration of the hair growth reducing agents that is well known in the art.

### ***Response to Arguments***

Applicant's arguments filed on June 16, 2005 have been fully considered but they are moot in view of new grounds of rejection in part and not persuasive in part.

Applicants now assert that Black fails to teach using AZT as a depilatory agent and instead teaches the nucleoside analogue to treat the tumors. Examiner respectfully disagrees, and views that the prior art makes a reference to the nucleoside analogues including AZT be used in an embodiment along with a vector "to destroy hair follicles".

### ***Conclusion***

No claims are allowed.

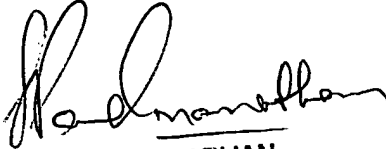
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



**SREENI PADMANABHAN**  
SUPERVISORY PATENT EXAMINER